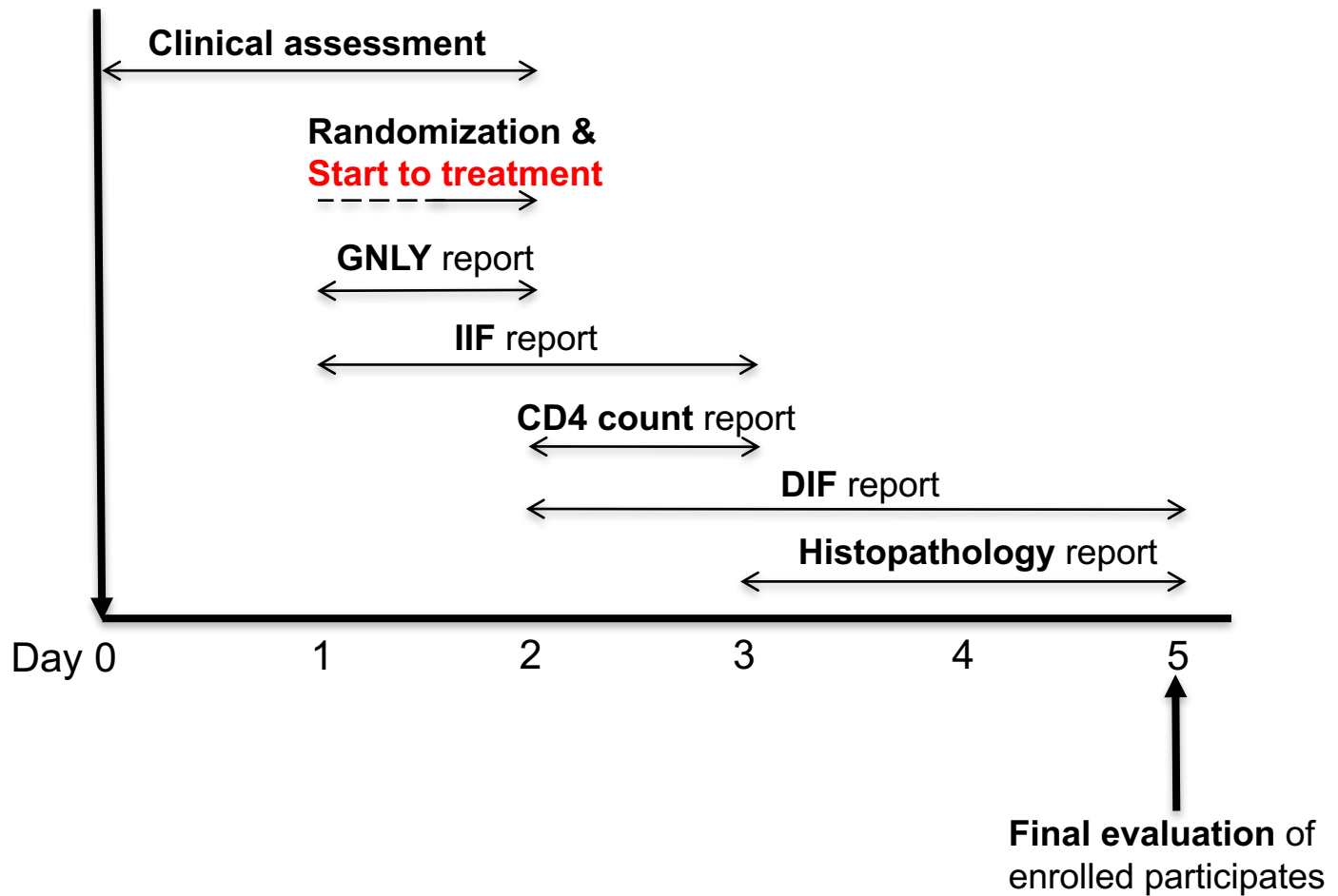


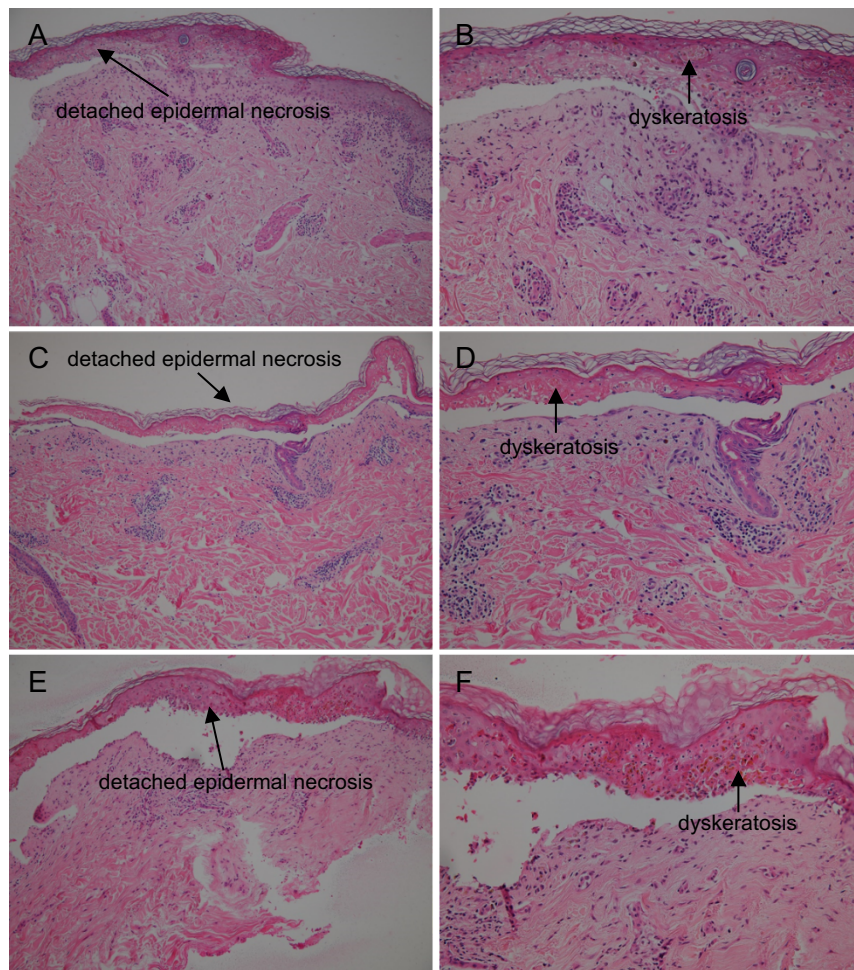
Supplemental Figure 1. The cell viability and cellular phenotypes of blister cells from patients with SJS/TEN for ex vivo study.

The cell viability and cellular phenotypes of blister cells were measured by flow cytometric assay. The cell types were determined as follow: keratinocyte cells, KRT⁺; fibroblasts, CD140a⁺; CD8⁺CTLs, CD45⁺CD3⁺CD8⁺ cells; NK cells, CD45⁺CD3⁺CD56⁺; NK T cells, CD45⁺CD8⁺CD56⁺; CD4⁺ T helper cells, CD45⁺CD3⁺CD4⁺; dendritic cells, CD45⁺CD11c⁺; B cells, CD45⁺CD20⁺; live cells, PI⁻ cells. Abbreviations: CTLs, cytotoxic T cells; KRT, keratin; NK cells, Natural killer cells; NKT cells, Natural killer T cells.



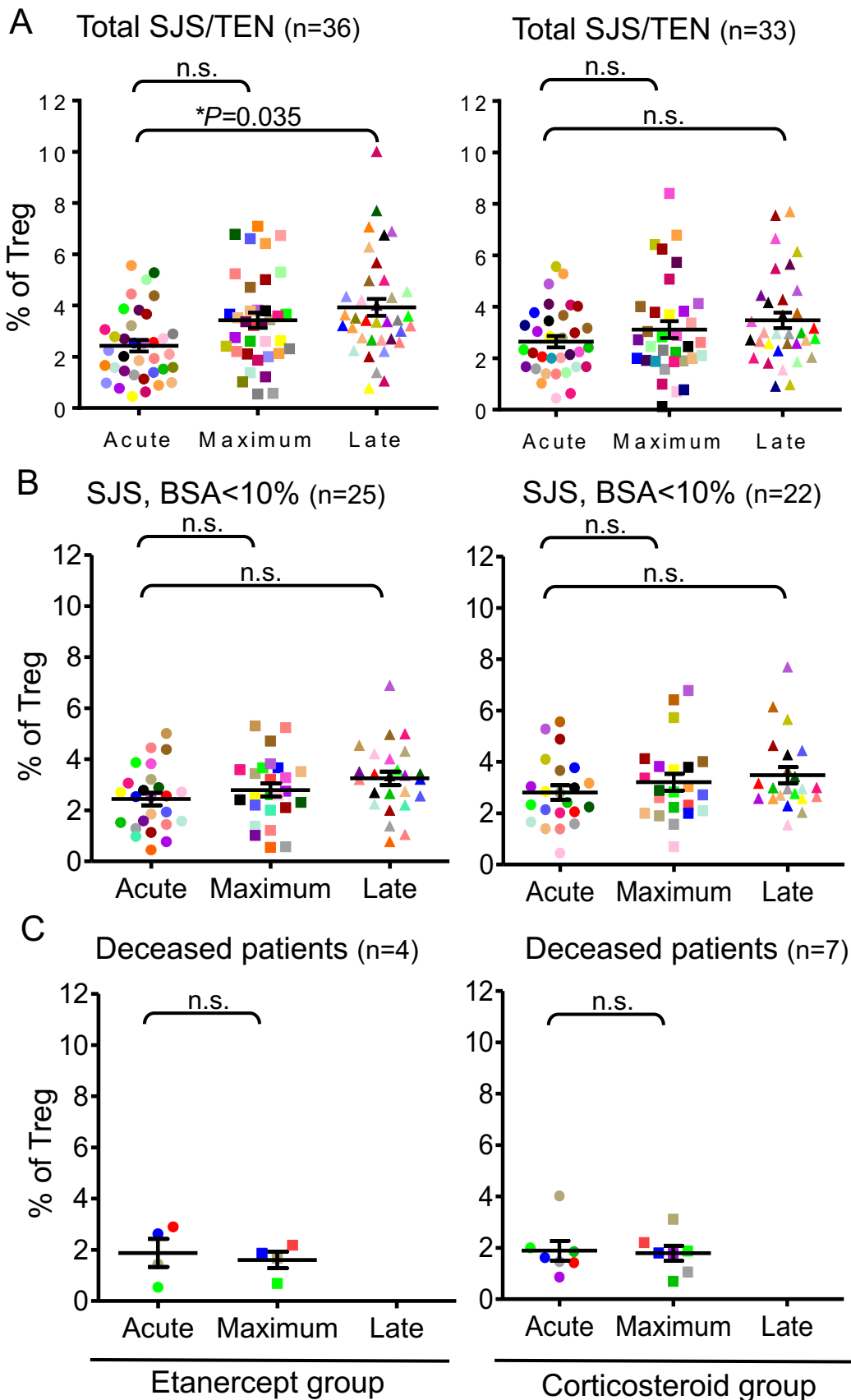
Supplemental Figure 2. Flow chart for determining the enrolled participants as SJS/TEN.

When the participants were admitted to hospital (Day 0), we initially diagnosed participants as SJS/TEN based on patients' skin phenotypes (e.g. epidermal necrosis, blister, widespread erythematous or purpuric macules/spots, mucosal erosions, and flat atypical target lesions). The diagnostic evaluation was further supported by laboratory examinations including reports of skin biopsies, blister GNLY level, IIF, and DIF to exclude other autoimmune bullous disease. The reports for GNLY, IIF, DIF and histopathology needed to take 1-2, 1-3, 2-5 and 3-5 days, respectively. Therefore, the final evaluation of participants as SJS/TEN needed to take 3-5 days. Since SJS/TEN is an emergent and life-threatening disease with rapid progression and need to be managed without delay, we considered starting necessary treatments for all enrolled SJS/TEN patients within 1-2 days. Furthermore, several patents failed a screening by low CD4 count (<200 cells/mm³; the report of CD4 count needed to take 2-3 days) after being allocated for specific treatment. Abbreviations: DIF, direct immunofluorescence; GNLY, granulysin; IIF, indirect immunofluorescence.



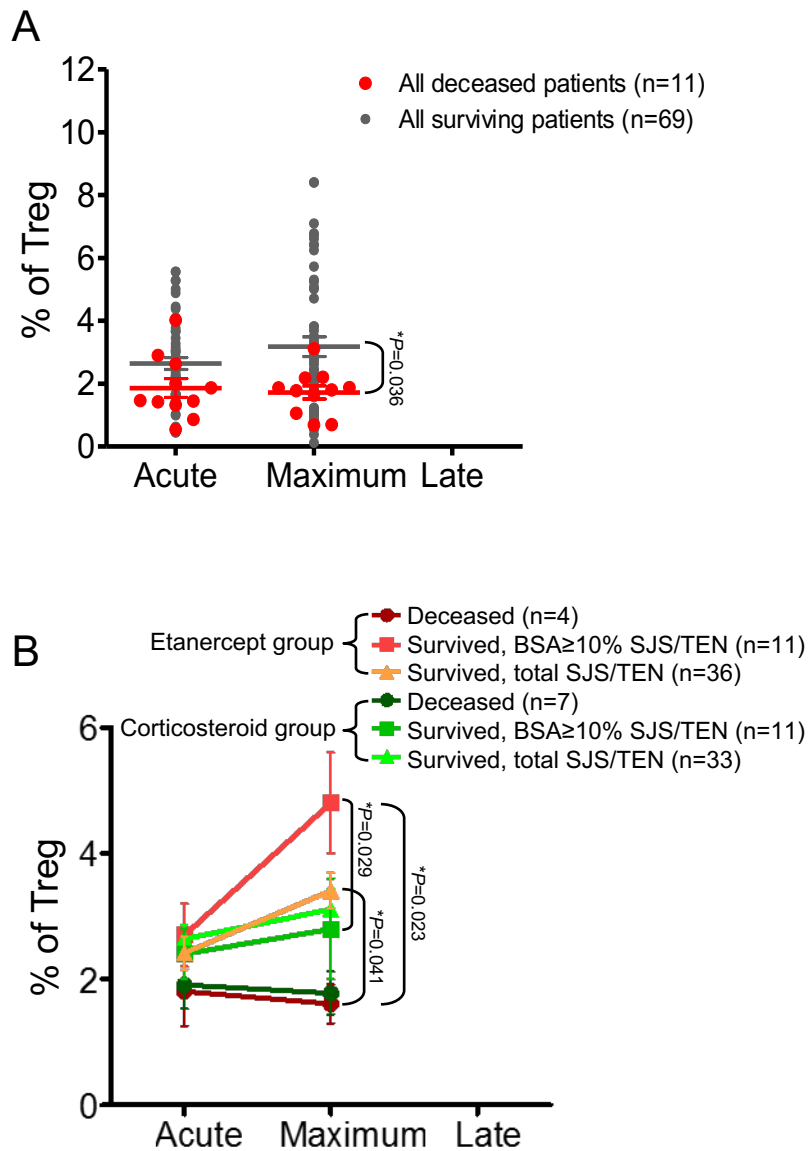
Supplemental Figure 3. The histopathologic features of SJS/TEN cases in the trial.

(A) and (B), detachment of necrotic epidermis with dyskeratosis is seen in a skin biopsy from an erythematous margin of blister in one SJS case (S053). The adjacent area revealed basket wave hyperkeratosis, focal parakeratosis, mild acanthosis, with dyskeratotic cells, exocytosis, vacuolar basal degeneration, and perivascular lymphocytes infiltration in dermis. (C) and (D), another biopsy taken from a SJS case (S079) showed partially detached necrotic epidermis and extensive necrosis of the superior portion of the epidermis with dyskeratosis, exocytosis, and vacuolated basal cells. (E) and (F), a biopsy specimen from a TEN case (S080) showed detached epidermal necrosis with numerous dyskeratotic cells, exocytosis, vacuolated basal cells and mild perivascular lymphocytic infiltrates with scattered neutrophils. Hematoxylin and eosin stain, original magnification, $\times 100$ (A, C, E); $\times 200$ (B, D, F).



Supplemental Figure 4. The Treg population in SJS/TEN patients during different stages after etanercept or corticosteroids treatment.

The population of CD4⁺CD25^{hi}Foxp3⁺Treg cells in the blood of total SJS/TEN patients (A), SJS patients with BSA detachment <10% (B), and deceased patients (C) were shown. Data are presented as the mean \pm SEM based on 2 independent experiments; *P* value was calculated by Student's *t*-test. **P*<0.05; n.s., nonsignificant.



Supplemental Figure 5. The correlation between Treg population and clinical severity in SJS/TEN patients.

The population of CD4⁺CD25^{hi}Foxp3⁺Treg cells in all deceased and all surviving patients (A), as well as in patients with SJS/TEN of different severities, including deceased patients, SJS/TEN with BSA detachment ≥ 10%, and total SJS/TEN (B) were shown. Data are presented as the mean ± SEM based on 2 independent experiments; *P* value was calculated by Student's *t*-test. **P* < 0.05.

Supplemental Table 1. Cellular phenotypes of blister cells from patients with SJS/TEN for *ex vivo* study.

Cell type	BC-1 %	BC-2 %	BC-3 %	BC-4 %	BC-5 %	BC-6 %	BC-7 %	BC-8 %	BC-9 %	BC-10 %
PI ⁻ live cells	86.91	99.60	98.89	90.44	69.81	70.90	89.59	98.42	91.67	90.87
Keratinocyte cells	23.93	18.23	35.93	5.93	10.23	15.21	17.78	59.97	19.58	23.04
Fibroblasts	1.97	3.2	2.76	2.03	3.21	0	0	0	2.10	1.00
CD45 ⁺ Immune cells	61.23	54.55	60.34	72.13	84.45	72.51	81.24	29.54	52.64	55.79
CD11c ⁺ Dendritic cells ^a	32.16	23.70	52.92	37.28	40.63	34.25	52.61	29.34	28.91	58.68
Lymphocytes	18.72	36.37	19.60	58.81	40.17	29.24	41.98	22.51	26.32	10.90
CD3 ⁺ CD8 ⁺ T cells ^b	61.31	35.43	45.38	16.05	55.31	54.31	58.51	54.31	66.79	68.26
CD3 ⁺ CD4 ⁺ T cells ^b	13.45	9.04	12.39	5.92	17.75	12.25	8.53	12.25	3.22	15.79
CD3 ⁺ CD56 ⁺ NK cells ^b	2.27	11.14	17.89	2.11	4.91	3.17	7.99	7.91	6.78	0.58
CD8 ⁺ CD56 ⁺ NKT cells ^b	22.87	25.51	8.89	20.06	27.59	19.89	17.91	5.89	34.77	26.32
CD20 ⁺ B cells ^b	2.65	2.46	0.80	8.10	6.30	3.43	10.38	9.85	0.47	5.12

NK cells, Natural killer cells; NKT cells, Natural killer T cells; PI, propidium iodide. ^a, The percentage was calculated on the basis of total CD45⁺ cells. ^b, This percentage was calculated on the basis of total CD45⁺ lymphocytes.

All the diagnostic criteria of SJS/TEN are based on the RegiSCAR study group and website (<http://www.regiscar.org/>). Abbreviations: EEMM, Erythema Exudativum multiforme major.

All the diagnostic criteria of SJS/TEN are based on the RegiSCAR study group and website (<http://www.regiscar.org/>). Abbreviations: EEMM, Erythema Exudativum multiforme major.

The diagnosis criteria of this table were made via the scoring system of clinical data (score A) and skin biopsy/photograph (score B).

Clinical data (Score A):

- (1). Target lesions
- (2). Skin pain
- (3). Positive Nikolsky sign
- (4). Skin detachment > 10% BSA or > 5cm
- (5). Erosion of mucous membrane
- (6). Diagnosis by a dermatologist

0: No erosion of mucous membrane, or skin detachment

1: Presentation at least with erosion of mucous membrane, or skin detachment, and fulfill 1 to 2 criteria for clinical data.

2: Presentation at least with erosion of mucous membrane, or skin detachment, and fulfill 3 to 6 criteria for clinical data.

Skin biopsy/photograph (Score B):

Skin biopsy:

0: Suggestive another disease; or skin biopsy was not done

1: Interface dermatitis/dyskeratosis

2: Partial epidermis gone

3: Full thickness epidermis necrosis

Photograph:

0: No erosions

1: Specific dermatitis

2: Erythema multiforme like

3: Full thickness epidermal necrosis without vascular lesions

Score B was obtained from the cross-table score system (see the middle of Supplemental Table 2).

After scores A and B were calculated, a final score was obtained from another cross-table score system (see the right middle of Supplemental Table 2).

A final score of 1, 2, and 3 was defined as a possible, probable, and definite case, respectively.

Supplemental Table 3. The participants that have not completely finished the study.

Reasons that not finished the study	Cases (n)
^a. Screen failure	
CD4< 200 cells/mm ³	3
Total	3
^b. Investigator decision	
Subject didn't comply with the use of medication	1
Total	1
^c. Others	
Combined corticosteroid to treat other acute diseases	4
Total	4
^d. Lost to follow-up	
Patient discharged against medical advice	1
Total	1
^e. Diagnosis change*	
Patient's symptoms are progressed to SJS/ AGEP overlapping	1
Patient is autoimmune bullous disease	1
Total	2
^f. During etanercept treatment, Patients died by	
Sepsis, respiratory failure	3
Asystole, respiratory failure	1
Total	4
^g. During corticosteroid treatment, patients died by	
Respiratory failure	2
Sepsis, respiratory failure	4
Sepsis, respiratory failure, severe respiratory acidosis, Do-Not-Resuscitate	1
Total	7

*Two cases had diagnosis changes. One was progressed to overlapping phenotype with SJS/ AGEP (acute generalized exanthematous pustulosis) (pathologic diagnosis: AGEP overlapping erythema multiforme), the other was considered as autoimmune bullous diseases based on positive for IIF and negative for GNLY report.

Supplemental Table 4. The clinical features and histopathologic characteristics of the trial participants

ID	Age	Sex	Group	BSA	Mucosa	Major pathologic findings	DIF	IIF	GNLY	RegiSCAR criteria				
										Score A	Score B	Final score	Class	RegiSCAR ID
S001	45	F	S	1	O	DE, DK, BV	Neg	Neg	ND	2	1	2	Probable	
S002	29	F	T	60	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810033
S003	35	F	T	8	O, E, G	PEN, DE, DK, BV, AD	Neg	Neg	Pos	2	3	3	Definite	8810034
S004	80	F	S	60	O, G	ND	ND	Neg	Pos	2	1	2	Probable	
S005	51	F	S	1	O, E, G	PEN, DE, DK, BV, AD	Neg	Neg	ND	2	3	3	Definite	8810035
S006	58	M	T	5	O, E	PEN, DE, SB, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810036
S007	76	M	T	50	O, E, G	DK, BV	Neg	Neg	Pos	2	2	2	Probable	
S008	61	M	S	25	O, E, G	PEN, DE, DK, AD	Neg	Neg	Pos	2	3	3	Definite	
S009	74	M	T	5	O	ND	ND	Neg	Pos	2	3	3	Definite	
S010	53	F	T	8	O	PEN, DE, DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810038
S011	58	F	T	1	O	PEN, DE, DK, BV, AD	Neg	Neg	Pos	2	2	2	Probable	
S012	85	F	S	5	O	ND	ND	Neg	Pos	2	1	2	Probable	
S013	31	F	T	7	O, E, G	PEN, DE, DK, BV	Neg	ND	Pos	2	3	3	Definite	8810037
S014	50	M	T	31	O, E, G	PEN, SB, DK	Neg	ND	Pos	2	3	3	Definite	8810048
S015	31	M	S	28	O, E, G	PEN, DE, DK	Neg	ND	Pos	2	3	3	Definite	8810049
S016	80	F	S	1	O	SB, DE, BV	Neg	Neg	Pos	2	3	3	Definite	
S017	49	F	T	72	O, E, G	SB, DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810051
S018	21	M	S	1	O, G	PEN, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810054
S019	75	F	T	60	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	
S020	42	M	T	8	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	2	2	Probable	
S021	49	F	T	50	O, E, G	DE, DK	Neg	Neg	Pos	2	3	3	Definite	
S022	66	M	S	1	O, G	DK, BV	Neg	Neg	Pos	2	1	2	Probable	
S023	7	M	T	1	O, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	
S024	63	F	S	1	O	DK, BV	Neg	Neg	ND	2	1	2	Probable	
S025	45	F	T	32	O, E	DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810056
S026	75	F	T	4	O, E	PEN, SB, BV	Neg	Neg	Pos	2	2	2	Probable	8810057
S027	38	M	T	1	O, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810059
S028	64	M	S	2	O	PEN, DE, DK, BV	Neg	Neg	Pos	2	2	2	Probable	
S029	41	F	T	70	O, E, G	ND	ND	ND	Pos	2	1	2	Probable	8810063
S030	75	M	S	50	O, E, G	ND	ND	Neg	Pos	2	1	2	Probable	8810065
S031	66	F	S	2	O, E, G	FTEN, DE	Neg	Neg	Pos	2	3	3	Definite	8810070
S032	35	F	T	1	O	ND	ND	ND	Pos	2	2	2	Probable	8810071
S033	15	M	S	1	O	SB, DK	Neg	Neg	Pos	2	2	2	Probable	8810073
S034	9	M	S	1	O, E, G	DK, BV	Neg	Neg	Pos	2	1	2	Probable	8810075

S035	71	M	T	4	O, E, G	FTEN, DE	Neg	Neg	Pos	2	3	3	Definite	8810078
S036	72	M	S	1	O, E, G	FTEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810083
S037	51	M	S	1	O, E	PEN, DK	Neg	Neg	Pos	2	2	2	Probable	8810085
S038	52	F	T	1	O, E	DE, SB, DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810081
S039	58	F	T	7	O, E	DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810082
S040	40	F	T	5	O, E, G	DE, DK	Neg	Neg	Pos	2	2	2	Probable	8810086
S041	86	M	T	1	O, E	PEN, DE, DK	Neg	ND	Pos	2	3	3	Definite	8810089
S042	70	F	S	1	O, E	DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810087
S043	82	F	S	9.5	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810091
S044	53	M	S	1	O, G	PEN, DE, DK, BV	Neg	Neg	ND	2	3	3	Definite	8810092
S045	70	F	T	5	O	DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810094
S046	47	F	T	31	O, E, G	FTEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810095
S047	83	M	S	7	O, E, G	DK, BV, AD	Neg	Neg	Pos	2	2	2	Probable	8810096
S048	68	F	T	95	O, G	PEN, DE, DK	Neg	Neg	Pos	2	2	2	Probable	8810103
S049	83	M	S	1	O, G	PEN, DE, SB, DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810104
S051	48	M	T	1	O	DK, BV	Neg	Neg	Pos	2	1	2	Probable	8810105
S052	48	F	T	50	O	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810017
S053	36	M	T	1	O, E, G	PEN, SB, DK, BV	Neg	ND	Pos	2	3	3	Definite	8810109
S054	81	F	S	5	O	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810110
S056	55	M	T	2	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810116
S057	84	M	S	9	G	PEN, DE, DK	Neg	Neg	Pos	2	3	3	Definite	
S058	84	M	S	2	O, E, G	SB, DK, BV	Neg	Neg	Pos	2	1	2	Probable	
S059	13	F	S	2	O, E	PEN, DE, DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810121
S060	40	F	T	1	O, E	DK, BV	Neg	Neg	Pos	2	2	2	Probable	8810122
S061	89	M	S	1	O	DK	Neg	Neg	ND	2	1	2	Probable	
S063	53	F	T	2	O	PEN, SB, DK	Neg	Neg	Pos	2	2	2	Probable	
S064	77	F	T	5	O, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810124
S065	72	M	T	3	O	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	
S066	34	M	S	25	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810126
S067	75	F	T	3	O, E, G	ND	ND	Neg	Pos	2	1	2	Probable	
S068	56	F	T	8	O, E	DK, BV	Neg	Neg	Pos	2	1	2	Probable	8810127
S069	47	M	T	9.5	O	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810131
S070	46	F	S	1	O, E	DK, BV	Neg	Neg	ND	2	1	2	Probable	8810132
S071	48	F	T	40	O, E, G	ND	ND	Neg	Pos	2	1	2	Probable	8810135
S072	84	F	S	1	O, G	PEN, DE, DK, BV	Neg	ND	Pos	2	3	3	Definite	8810137
S073	53	M	T	55	O, E, G	PEN, DE, DK	Neg	ND	Pos	2	3	3	Definite	8810138
S074	82	F	S	90	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810168
S075	66	M	S	50	O, E, G	PEN, DE, DK, AD	Neg	Neg	Pos	2	3	3	Definite	8810140
S077	82	F	S	27	O, E, G	ND	ND	ND	Pos	2	1	2	Probable	8810142
S078	61	F	T	2	O	BV	Neg	Neg	Pos	2	1	2	Probable	

S079	58	F	S	1	O, E	FTEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810147
S080	80	F	S	30	O, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810148
S081	13	F	S	20	O, E, G	PEN, DE, DK, BV	Neg	Neg	ND	2	3	3	Definite	8810149
S082	68	M	S	35	O, E, G	FTEN, DE, DK	Neg	ND	Pos	2	3	3	Definite	8810150
S083	34	M	T	1	O, G	PEN, BV	Neg	Neg	Pos	2	2	2	Probable	
S085	46	F	S	20	O, E, G	PEN, DE, DK	Neg	Neg	Pos	2	3	3	Definite	8810154
S086	65	M	T	5	O, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	8810162
C01	50	F	T	15	G	DE, DK,	Neg	Neg	Pos	2	3	3	Definite	
C03	46	M	T	13	O, E, G	PEN, DE, SB, DK, BV	Neg	Neg	Pos	2	3	3	Definite	
C09	43	M	T	15	O, E	PEN, DE, SB, DK, BV, AD	Neg	Neg	Pos	2	3	3	Definite	
C05	87	M	T	80	O, G	ND	ND	Neg	Pos	2	1	2	Probable	
C07	25	F	T	15	O, E, G	FTEN, DE, DK, BV	Neg	ND	Pos	2	3	3	Definite	
C04	41	F	S	25	O, E, G	PEN, DE, DK, BV	Neg	Neg	Pos	2	3	3	Definite	
C06	63	F	S	30	O, E, G	ND	ND	Neg	Pos	2	1	2	Probable	
C02	70	M	S	90	O, E, G	ND	ND	Neg	Pos	2	1	2	Probable	8810008
C10	77	F	S	60	O, E, G	ND	ND	Neg	Pos	2	1	2	Probable	
C08	6	F	S	50	O, E, G	FTEN, DE, DK	Neg	Neg	Pos	2	3	3	Definite	8810013

Three patients (S055, S062 and S084) failed a screening (<200 cells/mm³) and two patients served as diagnosis change (S050 and S076) were not included in the table. A total of 91 participants were validated as definite or probable SJS/TEN case by using the RegiSCAR criteria and histopathological examination. The diagnostic evaluation was further supported by laboratory examinations including skin biopsy with DIF, IIF using anti-intercellular substance and anti-basement membrane zone auto-antibodies (5) as well as blister granulysin level detection to exclude other autoimmune bullous diseases. A positive granulysin result was defined as >600 ng/ml in SJS/TEN patients (3). Abbreviations: AD, adnexal dyskeratosis or necrosis; BMZ, basement membrane zone; BV, basal vacuolation; BSA, body surface area detachment; Class, classification, DIF, direct immunofluorescence; DE, detached epidermis; DK, mass dyskeratosis; E, eye; FTEN, full thickness epidermal necrosis; G, genitalia; GNLY, granulysin; IIF, indirect immunofluorescence; ICS, intercellular substance; Neg, negative; ND, not done; O, oral cavity; PEN, partial epidermal necrosis; Pos, positive; RegiSCAR, european registry of severe cutaneous adverse reactions; S, corticosteroid; SB, subepidermal blister; T, tumor necrosis factor- α antagonist.

Supplemental Table 5. The clinical scoring system, “SCORTEN”, for predicting mortality in SJS/TEN.

Criteria (Individual score)	Cut-off value	SCORTEN (Sum of individual scores)	Predicted Mortality (%)
Age	≥40 yrs	0	3.2
History of malignancy	+	1	3.2
Heart rate	≥120/min	2	12.1
Initial % TBSA detachment	>10%	3	35.3
Serum urea nitrogen	>10 mmol/L (or >28 mg/dL)	4	58.3
Serum bicarbonate	<20 mmol/L (mEq/L)	>5	>90
Serum glucose	>14 mmol/L (or >252 mg/dL)		

Supplemental Table 6. Calculation of predicted mortality rates based on SCORTEN score.

SCORTEN (predicted mortality, %)	Etanercept n * predicted mortality, %	Corticosteroid n * predicted mortality, %
SCORTEN 0 (3.2%)	5*3.2=16	3*3.2=9.6
SCORTEN 1 (3.2%)	18*3.2=57.6	19*3.2=60.8
SCORTEN 2 (12.1%)	11*12.1=133.1	8*12.1=96.8
SCORTEN 3 (35.3%)	9*35.3=317.7	5*35.3=176.5
SCORTEN 4 (58.3%)	4*58.3=233.2	6*58.3=349.8
SCORTEN 5 (90%)	0*90=0	2*90=180
SCORTEN 6 (90%)	1*90=90	0*90=0
Sum	847.6	873.5
Predicted mortality, mean ± SD	17.7 ± 20.5	20.3 ± 25.1

Supplemental Acknowledgments for consortium details

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